

DECISION
no. 9/10.09.2014
on confirmation of adoption of NAMMD non-regulatory Scientific Council
Decisions, approved through written procedure

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the NAMMD President in the ordinary meeting of 10.09.2014, in accordance with Article 12 (5) of Emergency Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, hereby adopts the following

DECISION

Art. 1. – Adoption of the following NAMMD non-regulatory Scientific Council Decisions (SCDs), approved through written procedure, is approved:

- **SCD no. 3/10.05.2013** on approval of the priority assessment of marketing authorisation applications through national procedure for International Non-proprietary Names (INNs) determined in short supply on the pharmaceutical market

- **SCD no. 18/08.08.2013** on approval of the revised Guideline on evaluation of advertising of medicinal products for human use

- **SCD no. 19/12.08.2013** on approval of the detailed Guideline concerning the various categories of variations to the terms of marketing authorisations and on their examination by the National Agency for Medicines and Medical Devices by the purely national procedure for authorisation of medicinal products for human use, in accordance with Regulation (EC) no. 1234/2008 of the Commission, as amended through Regulation (EU) no. 712/2012

- **SCD no. 22/12.08.2013** on approval of abbreviated Romanian Standard Terms for the labelling of parenteral, eye, ear and nasal preparations, in line with European Pharmacopoeia approved terms

- **SCD no. 2/22.04.2014** on approval of Regulations for authorisation of sites for conduct of clinical trials on medicinal products for human use

- **SCD no. 5/05.06.2014** on adoption of the Guideline on Good Pharmacovigilance Practices – Annex I – Definitions, Rev. 2

- **SCD no. 6/05.06.2014** on approval of Regulations for authorisation by the National Agency for Medicines and Medical Devices of clinical trials/notification to the National Agency for Medicines and Medical Devices of non-interventional studies on medicinal products for human use in Romania.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim